

EcoScience Laboratories, Inc.

85 N. WHITNEY ST., P.O. BOX 300, AMHERST MASS. 01004 TEL. (413) 256-8984 FAX: (413) 253-2648

March 6, 1991

Susan Lewis (PM21)
Registration Division (H7505C)
Office of Pesticide Programs
United States Environmental Protection Agency
401 M Street S.W.
Washington, DC 20460

Re: Experimental Use Permit Application: Formulated *Mycoleptodiscus terrestris*, an aquatic bioherbicide for the control of Eurasian Watermilfoil *Myriophyllum spicatum*

Dear Ms. Lewis:

EcoScience Laboratories, Inc. requests Agency permission to perform testing using its bioherbicide containing *Mycoleptodiscus terrestris* (M.t.) mycelia to control Eurasian watermilfoil under a Section 5, EUP.

The field studies will be conducted according to the draft protocol (Volume 16) in Oregon, Minnesota, Washington, Michigan, Vermont, Alabama and Texas between April 1, 1992 and April 1, 1993.

As the use of formulated M.t., an indigenous microorganism, to control European watermilfoil is an aquatic outdoor non-food use, for an MPCA, the requirements for an EUP and full registration fall within the scope of Subdivision M of the Pesticide Testing Guidelines for a Microbial Pest Control Agent (MPCA) PB89-211676, March 1989.

Pre-EUP meetings were held with the Agency on June 8, 1989, December 14, 1989, and again on November 8, 1990, to determine the data requirements for an EUP and full registration of the product. We have now fulfilled what we believe are the data requirements for the EUP.

The requested protocols to determine:

1. which antifungal compounds would kill M.t. in the unlikely event that it did, in fact, infect and grow on mammals.
2. the appropriate dose in the mouse IP study to be used in the analysis of each production batch; and
3. the storage stability of the a.i. and the end use product

have been submitted in a separate document to you.

Five loose copies of the proposed label are enclosed.

Three meetings were held, June 8, 1989; December 14, 1989; and November 8, 1990. Copies of summaries sent to the EPA by EcoScience or our representative are enclosed, together with the EPA response (August 16, 1989 and February 13, 1990) to the first meeting. Our files do not contain responses to the December 16, 1989 meeting or the EcoScience Laboratories, Inc. letter of February 6, 1989, and no response has been sent by the EPA regarding the meeting of November 8, 1990 (EcoScience Laboratories, Inc. summary December 11, 1990).

Also enclosed (Attachment 4) are copies of correspondence between the EPA and EcoScience Laboratories, Inc. concerning the three meetings held to discuss and determine the data requirements for the EUP and full registration. Copies of these are also enclosed as appendices in the product chemistry volume, toxicology and ecotoxicology studies.

Contained in these volumes are the required Product Analysis/ Product Chemistry, Draft Label, Releasable Summary, Toxicology and Ecotoxicology, Summary of Efficacy Data and Proposed Experimental Program. As we believe this use does not require us to address the tolerance issue, no application for an exemption from tolerance has been made.

If there are questions please contact me.

Sincerely,



Anthony St.J. Green, Ph.D.
Vice President
Product Development & Regulatory Affairs

Enclosures: Attachment 1 - Application for an Experimental Use Permit,
Certification with Respect to Citation of Data
Attachment 2 - Transmittal Document, Data Reference Sheet
Attachment 3 - Agency/EcoScience Correspondence



United States Environmental Protection Agency
Office of Pesticide Programs
Registration Division (TS-767)
Washington, DC 20460

OPP Identifier Number

000599

Application for an Experimental Use Permit To Ship and Use a Pesticide for Experimental Purposes Only

1. Type of Application <input checked="" type="checkbox"/> New <input type="checkbox"/> Extension (Give Permit Number below) Permit Number		2. EPA Company Number 64296 - EOP - R	
3. Name and Address of Firm/Person to Whom the Experimental Use Permit Is To Be Issued (Include ZIP Code) EcoScience Laboratories, Inc. 85 N. Whitney St. Amherst, MA 01002		4. Name and Address of Shipper (If shipment is intended and if different from applicant's name and address)(Include ZIP Code)	
5. Name of Product Fungal Aquatic Herbicide		6. Is Product Registered with EPA? <input type="checkbox"/> Yes (Give Registration Number below) <input checked="" type="checkbox"/> No EPA Registration Number	
7. Total Quantity of Product Proposed for Shipment/Use 320 lb a.i.	8. Proposed Period of Shipment/Use April 1992 April 1993	9. Places from Which Shipped EcoScience Laboratories, Inc. 85 N. Whitney St. Amherst, MA 01002	

Certification

This is to certify that food or feed derived from the experimental program will not be used or offered for consumption or sale for consumption except by laboratory or experimental animals if illegal residues are present in or on such food or feed.

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

10. Specify the name & telephone no. of the individual most familiar with this application who can be contacted directly, if necessary to process this application. Tony St.J. Green 413-256-8984		11. Signature of Applicant or Authorized Firm Representative 	
		12. Title Vice President Product Dev. & Reg. Affairs	13. Date Signed 5/2/91

Below for EPA Use Only

In any correspondence on this application, refer to this number		Received by EPA-OPP Registration Division Washington, DC 20460
Normal review time indicates that processing of this application should be completed by (date)		
Name of EPA Contact	Telephone No.	

Draft E.U.P. LABEL

MT1 SELECTIVE AQUATIC BIOHERBICIDE

MT1

Granular Biological Aquatic Herbicide

For evaluation as an herbicide for management of Eurasian Watermilfoil in fresh water ponds, lakes, reservoirs, and drainage canals.

ACTIVE INGREDIENT:

Mycellium of *Mycoleptodiscus terrestris* ($\geq 10^4$ cfu/gram) 20%

INERT INGREDIENTS	80%
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Contains 3.2 oz. active ingredient per lb.

Total 100.0%

EPA Reg. No. 64296-EUP-XX

EPA Est. No. 64296-MA-XXX

CAUTION • PRECAUCION

Precaucion al Usuario: Si usted no lee ingles, no use este producto hasta que el etiqueta haya sido explicado ampliamente.

FOR EXPERIMENTAL USE ONLY

Not for sale or use by any person other than a participant or cooperator of the EPA-approved Experimental Use Program.

KEEP OUT OF REACH OF CHILDREN

CAUTION

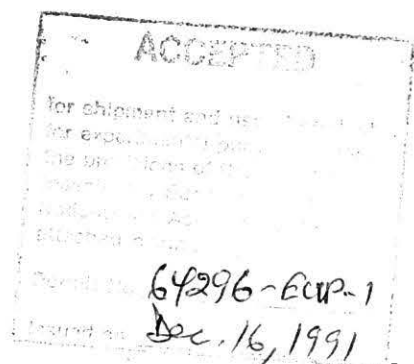
STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: FLUSH WITH PLENTY OF WATER.

GET MEDICAL ATTENTION IF IRRITATION PERSISTS.

WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING.

EcoScience Corporation
1 Innovation Drive
Worcester, MA 01605
(508) 754-0300



Net Contents: 54 pounds

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: CAUTION. Avoid contact with eyes, skin or clothing. Wear protective clothing such as eye goggles and rubber gloves during processing and application of the product. Do not use treated water for human or animal consumption or body contact recreational activities.

Statement of Practical Treatment: In case of contact with eyes or skin, flush eyes or skin with plenty of fresh water. If irritation persists get medical attention. If swallowed, drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

Environmental Hazards: Waters treated with MT1 are not to be used to irrigate crops. Do not eat or use fish, shellfish, or other animals or plants for feed from treated waters. Do not use treated water for drinking.

Mycoleptodiscus terrestris is a plant pathogen and exposure to nontarget plant species should be avoided. This product must not be applied to any sites which have endangered plant populations.

STORAGE AND DISPOSAL

Storage: Store in original container only. Do not store near or contaminate water, feed or food stuffs. To preserve the live active ingredient store at temperatures near 40°F. Do not freeze.

Pesticide Disposal: Waste resulting from the use of this product may be disposed of in accordance with applicable state or federal laws..

Container Disposal: Return container and any unused product to EcoScience Corporation, 1 Innovation Drive, Worcester, MA 01605.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Consult the appropriate state or local water authority before applying this product. Permits may be required by state or local public agencies.

GENERAL INFORMATION

MT1 is a selective granular mycoherbicide for the control of Eurasian Watermilfoil only. It is not corrosive to application equipment. MT1 is only effective on contact. It is important to obtain maximum contact with the target weed. Apply when weed is beginning to form a dense canopy. Avoid application to waters in rapid movement where granules will get dislodged. MT1 is a living organism that is an effective bioherbicide in water temperatures of 68 to 82°F. Plant control can take 3 to 6 weeks.

APPLICATION DIRECTIONS

Apply only when water temperatures reach 68 to 82°F. Do not apply above or below these temperatures. Do not mix with any other product.

For large areas, MT1 should be applied with a calibrated Gandy or Gerber spreader or similar equipment mounted on the back of a boat.

For small areas around docks or isolated patches of weeds, use a portable spreader such as the Cyclone seeder. To obtain uniform coverage, spread half of the total amount of MT1 in one direction and the second half at right angles to the first.

APPLICATION RATES

Pest	MT1	
	lbs/A	lbs/5000 ft ²
Eurasian watermilfoil (<i>Myriophyllum spicatum</i>)	0.5-50	0.12 - 5.76

CONDITIONS OF USAGE

Directions for Use of this product are believed to be adequate and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Risks associated with factors beyond the control of EcoScience Corporation (ESC) shall be assumed by the user.

ESC warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated therein subject to the inherent risks referred to above.

ESC MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESSED OR IMPLIED WARRANTY EXCEPT AS INDICATED ON THE LABEL. ESC SHALL IN NO EVENT BE RESPONSIBLE FOR DAMAGES, WHETHER DIRECT, INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL, AS A RESULT OF THE USE OR HANDLING OF THIS PRODUCT.

SECTION G

VOLUME 16

DATA REQUIREMENT

Volume 16: Section G. Proposed Experimental Program

AUTHOR

Patricia F. O'Leary, Ph.D.

PERFORMING LABORATORY

EcoScience Laboratories, Inc.
85 N. Whitney Street
Amherst, MA 01002

ESL PROJECT ID

Study Number: ESL SED 001

Experimental Use Permit Application: Formulated *Mycolep^{od}iscus terrestris*
for the control of *Myriophyllum spicatum*.

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA # 10 (d)(1), (A), (B), or (C).

Company: EcoScience Laboratories, Inc.

Company Agent: Anthony St.J. Green, Ph.D.


Date: 02/20/91

Vice President Product Development and Regulatory Affairs
(Typed Title)

ASJ Green
Signature

Submitted by: EcoScience Laboratories, Inc.
85 N. Whitney St.
Amherst, MA 01002
(413) 256-8984

Prepared by:


Patricia F. O'Leary, Ph.D.
Principal Author

2/20/91
Date

Approved by:

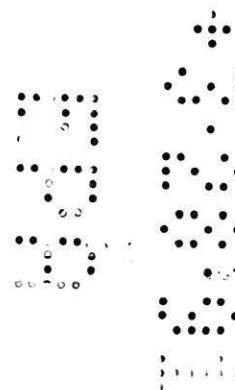

Anthony St.J. Green, Ph.D.
Program Manager

02/20/91
Date

VOL. 16: Proposed Experimental Program for MT1 Bioherbicide

I. Collaborators:

1. Jeffery J. Jenkins, Assistant Professor
Extension Specialist, Environmental Chemistry & Toxicology
Dept. of Agricultural Chemistry
Weniger Hall 237
Oregon State University
Corvallis, OR 97331-6502
(503) 737-5993; FAX: 737-0497
2. Kevin R. Kretsch
Lake Restoration, Inc.
620 Hamel Road
Hamel, Minnesota 55340
(612) 478-9421; FAX: 557-9979
3. Terrence M. McNabb, Vice President
Aquatics Unlimited N.W., Inc.
22647 88th Avenue South
Kent, Washington 98031
(206) 854-1420; FAX 872-6948
4. G. Douglas Pullman, Ph.D, Director of Research
CYGNET Enterprises, Inc.
1014 N. Bridge Street
P.O. Box 248
Linden, Michigan 48451
(313) 735-7910; FAX: 735-5422
5. Gerald N. Smith, President
Aquatic Biologist
6 Maple Street
P.O. Box 742
Northborough, MA 01532
(508) 393-8846
6. U.S. Army Corps of Engineers (ACE)
Waterways Experiment Station (CEWESER-A)
3909 Halls Ferry Road
Building 1006, Room 126
Vicksburg, MS 39180-6199



II. Proposed locations for field evaluation of MT1 bioherbicide:

Exact locations for field evaluation of MT1 bioherbicide within a state will be dependent upon suitable populations of Eurasian watermilfoil (EWM) at the beginning of each growing season. Therefore, exact sites cannot be specified. Proposed state locations are:

State	Acres	Lbs. M.t. a.i.
Washington	2	38.4
Massachusetts	2	38.4
Vermont	2	38.4
Oregon	2	38.4
Minnesota	2	38.4
Michigan	2	38.4
Texas	2	38.4
Alabama	2	38.4
Totals	16	307.2

III. Proposed program

The objective of these field studies is to determine MT1 application rates and timing under various geographic conditions. A single application of MT1 bioherbicide at 3 rates will be applied to Eurasian watermilfoil at two growth stages: Mid-growth (Early to late spring) and full canopy (Mid to late summer). One growth stage will be tested at each field site with total treated area/site equalling 1 acre. Timing will depend upon location of field sites. Procedures that will be followed, rates, etc. are detailed in the attached protocols (Appendix I).

IV. Proposed Data to be Collected

Plant biomass will be measured just prior to application and at 6 weeks post-treatment. Estimates of biomass reduction will be calculated. Also, visual estimates of reduction in EWM canopy will be made. EWM plants at sites in and out of the plot area will be tested for the presence of *M. terrestris* and proportion of plants infected with the fungus calculated.

V. Justification for quantity of MT1 requested

A. ONE FIELD SITE

Treatments:

1. MT1 @ 0.0 lb a.i./A
2. MT1 @ 0.5 lb a.i./A
3. MT1 @ 5.0 lb a.i./A
4. MT1 @ 50.0 lb a.i./A

Replication: 3

Area (1 acre = 43,560 ft²):

Control Plot Size: 50 X 100 ft = 5000 ft² = 0.115 A

Treatment Plot size: 50 X 100 ft = 5000 ft² = 0.115 A

(3 replicates X 0.115 A = 0.345 total A/site)

Material Required:

TRT	Acres	Lbs a.i.
MT1 @ 0.5 lb a.i./A	0.345	0.17
MT1 @ 5.0 lb a.i./A	0.345	1.73
MT1 @ 50.0 lb a.i./A	0.345	17.25
TOTALS	1.0	19.2

B. TOTAL a.i.

1. Number of field sites

Number of states: 8

Number sites/state: 2

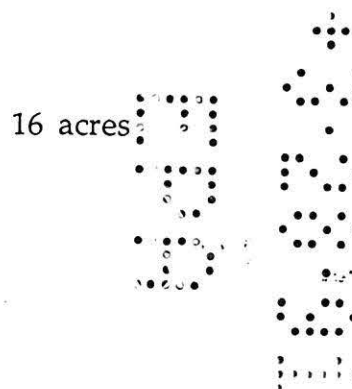
Total sites: 16 field sites

2. Number of acres

Number of field sites: 16

Total treated A/site: 1

Total acres: 16 acres



3. Active Ingredient

Number of field sites:	16.0	
Total pounds a.i./site:	19.2	
TOTAL a.i.		307.2 lbs a.i.
a.i. allowed for calibration, etc. (3.8 lbs a.i./site)		60.8 lbs a.i.
TOTAL		368.0 lbs a.i.

VI. Proposed duration of Experimental Use Permit

1 year: 1 April 1992 to 1 April 1993

VII. Disposition of unused MT1 bioherbicide

Any unused MT1 bioherbicide will be returned to EcoScience Laboratories for final disposition.

Draft E.U.P. LABEL

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MT1

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ACTIVE INGREDIENT:

Mycellium of *Mycoleptodiscus terrestris* ($\geq 10^4$ cfu/gram) 20%

INERT INGREDIENTS 80%

Contains 3.2 oz. active ingredient per lb.

Total 100.0%

EPA Reg. No. 64296-EUP-XX

EPA Est. No. 64296-MA-XXX

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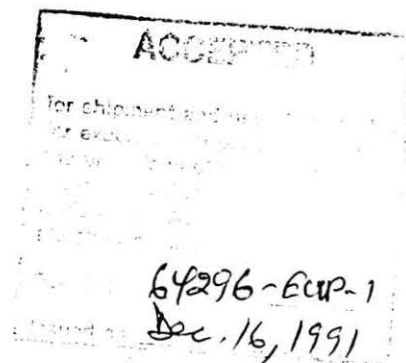
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EcoScience Corporation
1 Innovation Drive
Worcester, MA 01605
(508) 754-0300

Page 3 of 6



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ESC warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated therein subject to the inherent risks referred to above.

ESC MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESSED OR IMPLIED WARRANTY EXCEPT AS INDICATED ON THE LABEL. ESC SHALL IN NO EVENT BE RESPONSIBLE FOR DAMAGES, WHETHER DIRECT, INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL, AS A RESULT OF THE USE OR HANDLING OF THIS PRODUCT.

Transmittal Document

Name & Address of Submitter: EcoScience Laboratories, Inc.
85 N. Whitney Street
Amherst, MA 01002

Regulatory Action: Experimental Use Permit

Product Name: *Mycleptodiscus terrestris* mycelia

Registration No.: 64296-

Transmittal Date: February 13, 1991

List of Submitted Volumes:

- Volume 1:
- (I) Administrative Material
 - (II) Application for an Experimental Use Permit, Certification with Respect to Citation of Data
 - (III) Transmittal Document, Data Reference Sheet
 - (IV) Agency/EcoScience Correspondence
 - (V) 5 loose copies of the proposed label

SECTION A

Volume 2: 151A-10 to 151A-16: Gammon, D. W. and Green, A. St.J. (1990). *Mycleptodiscus terrestris*: Product Analysis/Product Chemistry

Volume 2A: 151A-10: Gammon, D.W. 1990. A Study on the Effect of Temperature on the Growth of *Mycleptodiscus terrestris* Hyphae

SECTION B

Volume 3: Draft Label

SECTION C

Volume 4: Releasable Summary

Volume 5a: 152A-10: Sherwood, R. L. (1990) IIT Research Institute. EPA Subdivision M Tier I, Acute Oral Toxicity/Pathogenicity Testing of *Mycleptodiscus terrestris*

Volume 5b: 152A-10: Sherwood, R. L. (1990) IIT Research Institute. Acute Oral Toxicity Limit Testing of *Mycleptodiscus terrestris*, a Fungal Herbicide

- Volume 6: 152A-12: Sherwood, R. L. (1990) IIT Research Institute, EPA Subdivision M Tier 1, Acute Pulmonary Toxicity/Pathogenicity Testing of *Mycoleptodiscus terrestris*, a Fungal Herbicide
- Volume 7: 152A-13: Sherwood, R. L. (1990) IIT Research Institute. Acute Intraperitoneal Pathogenicity of *Mycoleptodiscus terrestris*, a Fungal Herbicide
- Volume 8: 152A-15: Green, A. St.J. (1991). Survey of Hypersensitivity Incidents Involving *Mycoleptodiscus terrestris*
- Volume 9: 154A-16: Grimes, J. *et al* (1990) Wildlife International Ltd. *Mycoleptodiscus terrestris*: An Avian Oral Pathogenicity and Toxicity Study in the Mallard
- Volume 10: 154A-19: Swigert, J. P. (1990) ABC Labs, Inc. A 30-Day Static Renewal Toxicity and Pathogenicity Evaluation on the Effects of *Mycoleptodiscus terrestris* to Rainbow Trout (*Oncorhynchus mykiss*)
- Volume 11: 154A-19: Swigert, J. P. (1990) ABC Labs, Inc. A 30-Day Static Renewal Toxicity and Pathogenicity Evaluation on the Effects of *Mycoleptodiscus terrestris* to Bluegill (*Lepomis macrochirus*)
- Volume 12: 154A-20: Young, B. M. (1990) ABC Labs, Inc. 21-Day Prolonged Static Renewal Toxicity of *Mycoleptodiscus terrestris* to *Daphnia magna*
- Volume 13: 154A-20: Swigert, J. P. (1990) ABC Labs, Inc. A 21-Day Static Renewal Toxicity/Pathogenicity Test of Fungal Mycelium of *Mycoleptodiscus terrestris* to Midge (*Chironomus tentans*)
- Volume 14: 154A-22: Verma, U. and Charudattan, R. (1990) University of Florida. Toxicity/Pathogenicity Testing of Formulated *Mycoleptodiscus terrestris* on Nontarget Aquatic, or on Target Terrestrial and Endangered Aquatic Plants.

SECTION E

- Volume 15: Subdivision G [95-30, (12)]. Green, A. St.J. (1991). Summary of Efficacy Data Supporting EUP Application

SECTION G

- Volume 16: Proposed Experimental Program

Company Official: ASJ Green
Anthony St.J. Green
Vice President Product Development
and Regulatory Affairs

02/20/91
Date

Company Name: EcoScience Laboratories, Inc.

Company Contact: Anthony St.J. Green 413-256-8984